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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,759	11/11/1999	GISELA MEIER	2368/098	9841

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/438,759

Applicant(s)

MEIER ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 27, 30-35, 38, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoianovici et al., 6,337,994, in view of Wojciechowicz, 5,730,742.

Stoianovici discloses the invention substantially as claimed.

More specifically, as to claims 27 and 41, Stoianovici discloses a catheter (14, i.e., inner catheter, see column 2, lines 9-11); an electrically conductive rigid hollow tube (12) formed by a tube with a sharp tip (see column 2, lines 7-8, and column 6, lines 43-50) with an exit opening dimensioned for passage of a catheter (see Figure 2, and column 2, lines 7-12, a body part (proximal portion of 12, and see Figure 7) including an inlet opening axially aligned with the cannula tube, a connector electrically connected to the cannula in the area of the body part (see column 6, lines 43-50), wherein said cannula tube has an electrically insulating outer covering (34) of the cannula tube which extends from the body part out to the tip and which leaves the tip exposed at least in its

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distal end area (see Figure 6) and wherein said electrical connector (proximal portion of 12) extends through the body part to the outer surface of the cannula tube.

Stoianovici teaches that the cannula is formed of conductive metal, see column 3, line 4, and column 5, line 50. However, Stoianovici does not disclose that the metal is specifically steel.

Wojciechowicz also discloses a conductive cannula and discloses that the cannula is formed from steel, see column 6, lines 21-22. It would have been obvious to form the Stoianovici conductive cannula from steel as taught by Wojciechowicz as a known conductive metal or as an alternative to other conductive metals.

As to claim 31, the inlet of the body part decreases in diameter to form an inlet funnel oriented co-axially towards the proximal end of the cannula tube, see Figure 7.

As to claim 32, the proximal end of the body part has a luer-lock connection, see Figure 7.

Also, as to claim 30, Stoianovici does not disclose a ring gap is formed between the proximal end of the cannula tube and the thereto connected electrically contacting connector and an inner wall of the body part, and wherein said ring gap is filled with plastic.

However, it would have been obvious matter of design choice to modify the Stoianovici reference to include a ring gap filled with plastic, since applicant has not disclosed that the ring gap solves any stated problem or is for any particular purpose and it appears that the Stoianovici device without a ring gap would perform equally well as with a ring gap.

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As to claims 33, 38, Stoianovici does not disclose that the electrically exposed end area of the distal tip of the cannula tube has a length of maximally 1mm.

However, it would have been obvious matter of design choice to provide for an electrically exposed end area of the distal tip having a length of maximally 1mm since applicant has not disclosed that the claimed tip lengths solve any stated problem or is for any particular purpose and it appears that a tip of a different length would perform the disclosed functions equally well. Moreover, the optimum length can be determined by routine experimentation and thus would be obvious.

Also, as to claims 34, 35, 39, Stoianovici does not disclose specifically that the distal tip is a facet cut at an angle of approximately 45 degrees to the axis of the cannula tube. However, Stoianovici discloses that it is well known in the art to have a cannula terminate in a sharp edge, see column 2, lines 5-8). Such a sharp edge as known in the art would include a facet cut at an angle of 45 degrees as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 28, 29, are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoianovici et al., 6,337,994, in view of Mower et al., 4,765,341.

Stoianovici discloses the invention substantially as claimed (see above), except for an electrical contact pressed against the cannula tube, to which contact a wire of a multi-strand connector is soldered.

However, Mower et al. disclose a medical device having an electrode and an electrical contact connected to a wire of a multi-strand connector. Mower et al. teach that the multi-strand connector provides flexibility and has an exceedingly long life in the face of mechanical stress, see column 5, lines 45-56. It would have been obvious to provide a multi-strand connector as taught by Mower et al. as the connector in the Stoianovici device in order to provide for flexibility and to endure mechanical stress which is desirable for lasting use as taught by Mower et al.

3. Claims 36, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoianovici et al., 6,337,994, in view of Haindl, 4,889,529.

Stoianovici discloses the invention substantially as claimed, see above, except for the distal tip being formed as a closed conically arched tip with an exit opening, or a ramp is formed on the inside of the distal end of the cannula tube, or a Sprötte tip.

Haindl discloses a needle having such a tip. Since Stoianovici teaches that the distal tip may have a sharp tip as known in the art, and Haindl discloses a needle having

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a sharp tip, it would have been obvious to provide a sharp tip as disclosed by Haindl as a known sharp tip for a needle.

### ***Response to Arguments***

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. Examiner would like to point out that the Stoianovici device includes a catheter and a cannula that is unipolar (i.e., has one electrode).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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03/20/04